

EXHIBIT 8

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PHYSICIANS' DESK REFERENCE®

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Key to Controlled Substances Categories

Products listed with the symbols shown below are subject to the Controlled Substances Act of 1970. These drugs are categorized according to their potential for abuse. The greater the potential, the more severe the limitations on their prescription.

CATEGORY INTERPRETATION

- II** **HIGH POTENTIAL FOR ABUSE.** Use may lead to severe physical or psychological dependence. Prescriptions must be written in ink, or typewritten and signed by the practitioner. Verbal prescriptions must be confirmed in writing within 72 hours, and may be given only in a genuine emergency. No renewals are permitted.
- III** **SOME POTENTIAL FOR ABUSE.** Use may lead to low-to-moderate physical dependence or high psychological dependence. Prescriptions may be oral or written. Up to 5 renewals are permitted within 6 months.
- IV** **LOW POTENTIAL FOR ABUSE.** Use may lead to limited physical or psychological dependence. Prescriptions may be oral or written. Up to 5 renewals are permitted within 6 months.
- C** **SUBJECT TO STATE AND LOCAL REGULATION.** Abuse potential is low; a prescription may not be required.

Key to FDA Use-in-Pregnancy Ratings

The U.S. Food and Drug Administration's use-in-pregnancy rating system weighs the degree to which available information has ruled out risk to the fetus against the drug's potential benefit to the patient. The ratings, and their interpretation, are as follows:

CATEGORY INTERPRETATION

- A** **CONTROLLED STUDIES SHOW NO RISK.** Adequate, well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester of pregnancy.
- B** **NO EVIDENCE OF RISK IN HUMANS.** Adequate, well-controlled studies in pregnant women have not shown increased risk of fetal abnormalities despite adverse findings in animals, or, in the absence of adequate human studies, animal studies show no fetal risk. The chance of fetal harm is remote, but remains a possibility.
- C** **RISK CANNOT BE RULED OUT.** Adequate, well-controlled human studies are lacking, and animal studies have shown a risk to the fetus or are lacking as well. There is a chance of fetal harm if the drug is administered during pregnancy; but the potential benefits may outweigh the potential risk.
- D** **POSITIVE EVIDENCE OF RISK.** Studies in humans, or investigational or post-marketing data, have demonstrated fetal risk. Nevertheless, potential benefits from the use of the drug may outweigh the potential risk. For example, the drug may be acceptable if needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective.
- X** **CONTRAINDICATED IN PREGNANCY.** Studies in animals or humans, or investigational or post-marketing reports, have demonstrated positive evidence of fetal abnormalities or risk which clearly outweighs any possible benefit to the patient.